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| 09/928,367 | 08/14/2001 | David Duffy | 11641/36 | 6423 |

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KENYON & KENYON
1500 K STREET, N.W., SUITE 700
WASHINGTON, DC 20005

| EXAMINER |
|---|
| WESSENDORF, TERESA D |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1639 | |

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/928,367 | Applicant(s) DUFFY, DAVID | |
|---|---|---|---|
| | Examiner T. D. Wessendorf | Art Unit 1639 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *At ap3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *27 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *8-22,30-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-7, 23-29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-11 and 32 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that Group I and III should be examined together. While applicants do not concede that groups I and III represent patentably indistinct subject matter, applicants submit that the two inventions define sufficiently related subject matter so as to justify examination together in a single application. Applicants further argue that claim 23 recites a step of detecting binding of biomolecules in solution to the immobilized biomolecules. And, claim 1 recites a step of "detecting modification of immobilized biomolecules". One can detect modification of immobilized biomolecules as recited in claim 1 by detecting whether there exists binding of biomolecules in solution to the immobilized biomolecules. In view of applicants' implicit admission that Groups I and III are patentably indistinct subject matter, the restriction is revised. The two inventions I and III will be examined together.

Applicants' election of the species "detecting the presence of at least one biomolecule in solution" is acknowledged. Applicants argue that the species comprising the additional steps merely further the respective independent claims. In

response, because the method includes other additional steps hence, it does not further limit the independent claims. [A species restriction seems proper for the different steps encompassed by the method. Rather, than different groups for the single method].

Claims 8-22 and 30-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Claims 1-7, 23-39 and 32 are under examination

***Specification***

The abstract of the disclosure is objected to because it is too long. Also, because of the use of phraseology often used in patent claims "comprising". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of **50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The disclosure is objected to because of the following informalities: the status of application Serial No. 09/705,187 at page 9, line 9 is missing.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112, first paragraph***

Claims 1-7, 23-29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate written description of the claimed invention. The claimed invention recites for numerous undefined or unknown variables such as "biochemical pathways", "array of immobilized biomolecule" and

biomolecule in solution" and analysis of the modified biomolecule pathway. The disclosure provides a definition for each of these variables. The disclosure also provides a list of the different compounds encompassed in each of the variables. However, the specification fails to describe which biomolecules from the list can be made either singly or in combination with one another to form an array. A single array can include millions of the same or different biomolecules like protein, nucleic acids, carbohydrates or lipids. The specification does not describe which of these different biomolecules have been made into a single array. More importantly, how such array can prevent interaction of the molecules therein such that binding is only to the target. This problem is made more complex for an array in solution. It does not describe the step by which the different components are separated or identified when in solution. It does not provide molecular level information on how proteins interact to control cell behavior and physiology. This is especially so in view of the boundless network of a biochemical pathway. It is a sequential collection of processes or reactions a cell uses to transmit stimuli. Each of processes or reactions usually involves a series of interactions between two or more biomolecules. One biomolecule may modify the other such that the modified biomolecule is activated or inactivated.

Thus, mere listing the components of an array does not equate to a specific description of the biomolecules collectively. The specific description in the specification relates to kinase and its pathway as rAfk. In the analysis of biomolecule pathway, where every inconceivable reaction occur along the way, one skilled in the art would not have deemed the specific description sufficient. The specific written description is so specific that would lead one skilled in the art only to that specific pathway for a biomolecule.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 23-29 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the method of detecting the

modification. It is unclear how the mere steps of formation and exposure of the immobilized biomolecules to a solution results in modification of the immobilized biomolecule. If any, the kind of modification detected. There is no nexus between the preamble of analyzing a biochemical pathway and the body of the claim reciting detecting the modification of the immobilized biomolecules. "Formation" is not a positive, manipulative process step. -Forming—is suggested. The phrase "and/or" is indefinite as to which biomolecules together or separate can detect a single or separate pathway.

B. Claims 2, 3, 24 and 25 are indefinite as to the metes and bounds of the different types of immobilized biomolecules, especially in the absence of positive showing in the specification.

C. Claims 4-7 and 26-29 are indefinite as to the additional detecting step of a biomolecule in solution. This would broaden the base claim 1, which recites for detecting the immobilized biomoleucle. Also, the step of identifying the function of a biomolecule broadens the base claim 1. It is suggested that these steps be incorporated into the independent claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

> art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 23-29 and 32 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Borrebaeck et al (2001/0053520).

Borrebaeck et al discloses at page 7, paragraph [0080] a method comprising creating an array of immobilized antibodies (biomolecules as claimed) including printing on a solid surface using pins or spotting with individual drops of solution. Antigen preparation from a tumor tissue, that may be a complex mixture of antigens, is then subjected to the array and antigens will bind to their corresponding antibodies on the array. Bound antigens are then detected. To get informative data another antigen preparation from the normal counterpart to the tumor tissue is then subjected to an identical array as was used for the tumor tissue. Spots that differ between the two tissues represent antigens that are differentially expressed in the two tissues. At paragraph [0104] it is disclosed that the methods provide a way to study variation in protein content globally involving chip or array technologies. And, generates a large enough number of probes that can be used for array that have the potential to discriminate between post-translationally modified variants of proteins or polypeptides caused by e.g. differential

glycosylation or phosphorylation (biochemical pathways, as claimed).

Therefore, the broad claimed invention comprising unknown components and broad process steps is anticipated or obvious over the teachings of Borrebaeck et al. Borrebaeck discloses a method reciting specific components and specific process steps, as stated above. [The claim as broadly written is subject to several interpretations.]

Claims 1-7, 23-29 and 32 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Felder et al (6,232,066 equivalent to WO 9932663).

Felder et al discloses at Example 17, a method by which a probe comprising a linker that are phosphorylated peptides covalently attached to oligonucleotides. The peptide moieties are selected for their ability to bind to a group of selected SH2 proteins. The linkers bound substrates are ligands specific for the group of SH2 proteins (biochemical pathways as claimed). The proteins are isolated and labeled with, for example, a cy5 fluorescent molecule. To screen for inhibitors of the SH2 domain/phosphopeptide interaction, the group of labeled SH2 proteins is added to each well of the

substrate bound linkers, (i.e., 100 96-well MAPS plates), and in each well a different test compound is added. The effect of each compound individually on the interaction of the SH2 proteins with their phosphopeptide ligands is tested. The assay measures the fluorescence of bound SH2 protein associated with each surface-bound peptide linker. For screening, the five kinases at appropriate concentrations are added to each well along with one of 8800 different compounds to be tested. The compounds are tested for their ability to directly inhibit the isolated enzymes. The amount of phosphorylation of each arrayed peptide is detected by adding labeled antibodies that bind only to peptides that are phosphorylated on tyrosine. Any wells that show reduction in some of the phospho-tyrosine spots but not all of the spots are of interest. Compounds that had been added to those wells can be tested further as possible selective inhibitors of some of the kinases tested. See also the claims. The claims recite a method comprising contacting a sample which may comprise said target(s) with a nuclease protection fragment(s) specific for and which binds to said target(s), exposing the sample to a nuclease effective to digest remaining single strand nucleic acid, and then contacting the resultant sample with a combination which comprises, before the addition of said sample, i) a surface comprising multiple spatially

discrete regions, at least two of which are substantially identical, each region comprising ii) at least two different anchors, each in association with iii) a bifunctional linker which has a first portion that is specific for the anchor, and a second portion that comprise a probe which is specific for said nuclease protection fragment(s), under conditions effective for said nuclease protection fragment(s) to bind to said combination, and detecting said bound protection fragment(s). Therefore, the broad claimed invention comprising unknown components and broad process steps is anticipated or obvious over the teachings of Felder et al. Felder discloses a method reciting specific components and specific process steps, as stated above.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A. Chin et al discloses a method of detecting proteins using arrays.

B. Ruggieri et al discloses cell-signaling polypeptides and nucleic acid.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
February 21, 2003